

REMARKS

Claims 10-20 currently are pending.

Claim 10 currently has been amended so that the homo- or copolymers of N-vinylpyrrolidone are defined as water-soluble polymers with a Fikentscher K value of 12 to 100. The support for this amendment can be found on page 3, lines 15-20.

Claims 10-12 and 14-20 are rejected under 35 USC § 103(a) as being obvious over the combined disclosures of Staniforth et al. (US 5,741,524), Sutton et al. (US 5,993,805), and Groenendaal et al. (5,264,222). The examiner believes it would have been obvious to one of ordinary skill in the art to combine the disclosures of the above references because one would have seen from Groenendaal et al. that cross-linked PVP is a well-known disintegrant and is easily substitutable with microcrystalline cellulose.

First, applicants believe the office action mailed on May 13, 2004 should not have been a final office action. The examiner stated on page 5, item 10, that applicants' amendment necessitated the new ground(s) of rejection presented in this office action. Applicants respectfully disagree.

Applicants amended claim 10 in the last response (February 9, 2004) by incorporating the limitations of claim 13. The examiner uses a new reference now in the present office action (May 13, 2004): Groenendaal et al. (US 5,264,222). Applicants do not see how adding the limitation "wherein the polymer in the excipient is a homo- or copolymer of N-vinylpyrrolidone" to claim 10 necessitates the new obviousness rejection using this new reference, Groenendaal et al. The examiner has

issued an obviousness rejection using a new reference. Accordingly, applicants request withdrawal of the finality of the office action dated May 13, 2004.

Applicants furthermore respectfully traverse the 35 USC § 103(a) rejection.

Applicants believe the examiner has not established a *prima facie* case of obviousness.

In order to complete the PTO's *prima facie* case and shift the burden of going forward to applicant, there must be evidence (other than speculation by the PTO) that one of ordinary skill in the subject art would have been motivated to make the modification of the prior art necessary to arrive at the claimed subject matter. *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941, 1944 (Fed. Cir. 1992).

The examiner argues that it would have been obvious to one of ordinary skill in the art to substitute cross-linked polyvinylpyrrolidone known from Groenendaal et al. for microcrystalline cellulose because both cross-linked PVP and microcrystalline cellulose were known to be disintegrants.

Applicants believe one of ordinary skill in the art would not have made the modifications as the examiner suggests because it is not the subject of the present invention to provide for an excipient with disintegrant properties. The PVP types used according to the present invention are not a cross-linked PVP, but water-soluble polymers with a defined K value which do not act as a disintegrant. Cross-linked PVP is not soluble in water and since it is cross-linked, it does not possess a K value. Also, the problem to be solved by the claimed invention is a different one. The subject of the present invention to provide for improved method for processing liquid or semi-solid surfactants.

In view of the above, applicants believe the examiner has engaged in prohibited hindsight reasoning to arrive at the present invention. To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. *W. L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

Also in view of the above, a substitution of cross-linked PVP for microcrystalline cellulose does lead to the claimed excipients as presently amended because cross-linked PVP is not soluble in water. Since it is cross-linked, it does not possess a K-value. Claim 10 has been amended to include a K value. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

The examiner argues that the selection of a specific surfactant is suggested by the disclosure of Sutton et al. The examiner believes that with this in mind one of ordinary skill in the art would have included the cross-linked PVP and also combined the surfactant known from Sutton et al. to provide proper stability of the excipient.

Applicants respectfully disagree. Although it may be known from Sutton et al. that PVP and specific surfactants can be used together in pharmaceutical formulation, Sutton et al. teach the manufacture of active ingredient containing hollow microcapsules. Sutton et al. do not refer to excipients which do not contain an active ingredient.

For the reasons expressed above, it is urged that the prior art references cited by the examiner either singly or in combination fail to anticipate or suggest the present invention as defined by the amended claims. Accordingly, a *prima facie* case of obviousness has not been established by the examiner, and the rejection under 35 USC § 103 should be withdrawn.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such account.

Respectfully submitted,
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